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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,303	11/27/2001	Robert C. Beck	2446	1374
7	05/12/2003			
Beck & Tysver, P.L.L.C.			EXAMINER	
2900 Thomas Avenue S., Suite 100 Minneapolis, MN 55416			DESANTO, MATTHEW F	
			ART UNIT	PAPER NUMBER
			3763	^
			DATE MAILED: 05/12/2003	9

Please find below and/or attached an Office communication concerning this application or proceeding.

[-		Application No.	Applicant(s)				
,		09/995,303	BECK, ROBERT C.				
	Office Action Summary	Examiner	Art Unit				
		Matthew F DeSanto	3763				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1)⊠ R	esponsive to communication(s) filed on 28 F	<u>ebruary 2003</u> .					
2a)⊠ TI	nis action is <b>FINAL</b> . 2b)☐ Thi	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims							
4)⊠ Claim(s) 7-9, 18-24, and 27-30 is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
·							
	6)⊠ Claim(s) <u>7-9,18-24 and 27-30</u> is/are rejected.						
l '_	nim(s) is/are objected to.	r alaction requirement					
8) Claim(s) are subject to restriction and/or election requirement.  Application Papers							
	specification is objected to by the Examine	r.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) ☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
2) Notice of	References Cited (PTO-892) Draftsperson's Patent Drawing Review (PTO-948) on Disclosure Statement(s) (PTO-1449) Paper No(s) _	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)				
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#### **DETAILED ACTION**

## Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the sheath partially blocking the collection vessel must be shown or the feature canceled from the claims. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

## Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "said sheath partially blocking the vessel but allowing some blood flow in the vessel."

## Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 4. Claims 7 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. The examiner does not understand and cannot find any description in the specification on how the sheath partially blocks the collection vessel.

5. The 112 rejection in Paper number 6 is withdrawn because of the amendment made the Applicant.

# Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 7-9, 18-24, 27, 28, 30, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Neracher (5135482).

Neracher discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figures 1, 3, 4, 10, 11, 12, 13, and entire reference)

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As to claim 18, wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath. (Figure 4, 12, 13 and entire reference)

As to claim 9, wherein said fluid is injection at a first injection pressure above the blood pressure in the vessel and expands to second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen. (Column 3, line 53 – Column 4, line 15)

As to claim 27, wherein said primary fluid is supplied by a supply syringe chamber and said discharge lumen is coupled to syringe vacuum chamber, and said supply syringe and vacuum syringe are operated together to couple fluid supply with discharge lumen collection. (Figure 3, entire reference)

3. Claims 7-9, and 18-24, 27, 28, 30, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Carbo et al. (UPSN 5250060).

Carbo et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figures 1, 2, 3, 4, 5, and entire reference)

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As to claim 18, wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath. (Figures 1, 2, 3, 4, 5, and entire reference)

As to claim 9, wherein said fluid is injection at a first injection pressure above the blood pressure in the vessel and expands to second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen. (Figures 1, 2, 3, 4, 5, and entire reference)

As to claim 27, wherein said primary fluid is supplied by a supply syringe chamber and said discharge lumen is coupled to syringe vacuum chamber, and said supply syringe and vacuum syringe are operated together to couple fluid supply with discharge lumen collection. (Figures 1, 2, 3, 4, 5, and entire reference)

4. Claims 7 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (UPSN 5100425).

Fischell et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen.

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# Response to Arguments

5. Applicant's arguments filed 2/28/03 have been fully considered but they are not persuasive.

6. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., excluding a proximal balloon on the sheath) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore the rejection of Neracher, and Cabo still stand.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.

SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700

Matthew DeSanto Art Unit 3763 May 5, 2003

MUHALL